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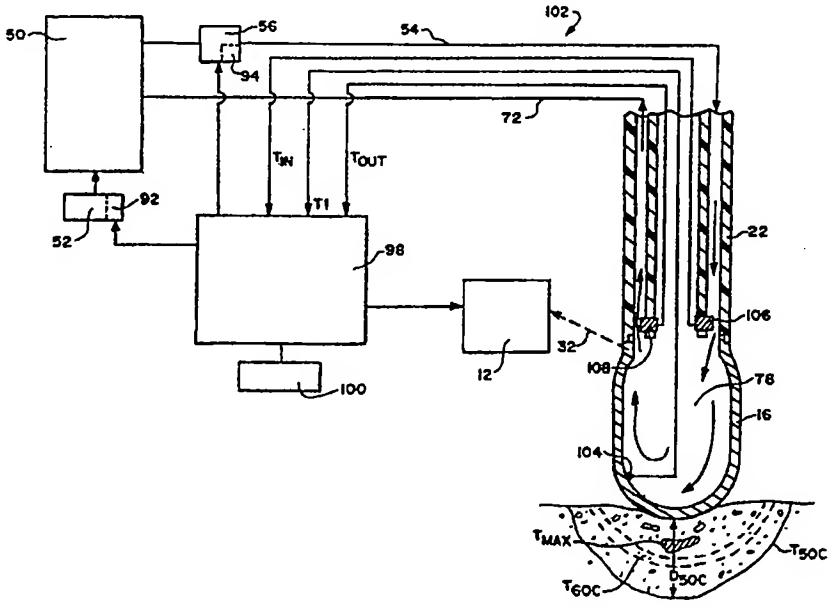


(57) Abstract

This invention is systems and methods that ablate body tissue using an electrode (16) for contacting tissue at a tissue electrode interface to transmit ablation energy at a determinable power level. The systems and methods include an element (50) to remove heat from the electrode (16) at a determinable rate. The systems and methods employ a processing element (98) to derive a prediction of the maximum tissue temperature condition occurring beneath the tissue electrode interface. The processing element (98) controls the power level of ablation energy transmitted by the electrode (16), or the rate at which the electrode (16) is cooled, or both, based, at least in part, upon the maximum tissue temperature prediction.

SYSTEMS AND METHODS FOR ABLATING BODY TISSUE USING PREDICTED MAXIMUM TISSUE TEMPERATURE

Field of the Invention

In a general sense, the invention is directed to systems and methods for creating lesions in the interior regions of the human body. In a more particular sense, the invention is directed to systems and methods for ablating heart tissue for treating cardiac conditions.

Background of the Invention

Physicians frequently make use of catheters today in medical procedures to gain access into interior regions of the body. In some procedures, the catheter carries an energy transmitting element on its distal tip to ablate body tissues.

In such procedures, the physician must establish stable and uniform contact between the energy transmitting element and the tissue to be ablated. Upon establishing contact, the physician must then carefully apply ablating energy to the element for transmission to the tissue.

The need for precise control over the emission of ablating energy is especially critical during catheter-based procedures for ablating heart tissue. These procedures, called electrophysiology

In a preferred embodiment, the processing element samples the power level at which the electrode transmits ablation energy and the temperature of the electrode to derive the maximum tissue temperature prediction.

In another preferred embodiment, the processing element samples the power level at which the electrode transmits ablation energy , the temperature of the electrode, and the rate at which heat is removed from the electrode to derive the maximum tissue temperature.

In another preferred embodiment, the processing element retains a function that correlates an observed relationship among maximum tissue temperature below the tissue-electrode interface and a set of predetermined operating conditions. In this embodiment, the processing element samples an actual operating condition and compares the actual operating condition to the function. The processing element derives from the comparison the prediction of the maximum tissue temperature.

Other features and advantages of the inventions are set forth in the following Description and Drawings, as well as in the appended claims.

Brief Description of the Drawings

Fig. 1A is a system for ablating tissue using an actively cooled ablation electrode and associated cooling medium delivery system that embodies the features of the invention;

Fig. 1B is a diagrammatic view of a lesion profile, without an actively cooled ablation electrode;

Fig. 1C is a diagrammatic view of a lesion

that adjusts the level of RF power delivered to a cooled electrode based upon the sensed electrode temperature and the rate that ablation power is conveyed into the tissue through the cooled electrode;

Fig. 9B is a diagrammatic view of a neural network that can be used in association with the system shown in Fig. 9A;

Fig. 10 is a side section view of an actively cooled energy transmitting electrode that can be associated with the system shown in Fig. 1A, showing an outward projecting, blunt end temperature sensing element carried within a heat conducting cap by the electrode for sensing tissue temperature below the tissue surface;

Fig. 11 is an exploded side view of the temperature sensing element shown in Fig. 10;

Fig. 12 is a side section view of an actively cooled energy transmitting electrode that can be associated with the system shown in Fig. 1A, showing an outward projecting, pointed end temperature sensing element carried within a heat conducting cap by the electrode for sensing tissue temperature below the tissue surface;

Fig. 13 is a side section view of an actively cooled energy transmitting electrode that can be associated with the system shown in Fig. 1A, showing a movable temperature sensing element carried within a heat conducting cap by the electrode, the sensing element being shown in its retracted position within the electrode;

Fig. 14 is a side section view of the energy transmitting electrode shown in Fig. 13, showing the movable temperature sensing element in its extended position projecting into tissue;

the tissue surface;

Fig. 20 is a section view of a motor driven stylet used to adjust the position of the movable temperature sensing element shown in Figs. 13 and 14, with an associated feedback controller that seeks the region of highest sub-surface tissue temperature;

Fig. 21 is a diagrammatic view of an apparatus for acquiring experimental data to create a function that correlates a relationship among lesion boundary depth, ablation power level, ablation time, maximum tissue temperature, and electrode temperature that can be used by a processing element to control an ablation procedure to target lesion characteristics; and

Fig. 22 is a diagrammatic flow chart showing a process that the feedback controller for the motor driven stylet shown in Fig. 20 can use to position the temperature sensor in the region of highest sub-surface tissue temperature.

The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

Description of the Preferred Embodiments

Fig. 1A shows a system 10 for ablating human tissue that embodies the features of the invention.

In the illustrated and preferred embodiment, the system 10 includes a generator 12 that delivers radio frequency energy to ablate

22, and a catheter distal section 24, which carries the electrode 16.

The handle 20 encloses a steering mechanism 26 for the catheter tip 24. A cable 28 extending from the rear of the handle 20 has plugs 30. Some of the plugs 30 are coupled to a signal wire 32(see Fig. 2A) that extends from the ablation electrode 16 through the catheter body 22. The plugs 30 connect to the generator 12 for conveying radio frequency energy to the ablation electrode 16 through the wire 32.

Left and right steering wires 34 (also see Fig. 2A) extend through the catheter body 22 to interconnect the steering mechanism 26 in the handle 20 to the left and right sides of a deflecting spring element 36. Rotating a steering lever 38 on the handle to the left causes the steering mechanism 26 to pull on the left steering wire, causing the spring element 36 to bend to the left (as shown in phantom lines in Fig. 1A). Similarly, rotating the steering lever 38 to the right causes the steering mechanism 26 to pull on the right steering wire 34, causing the spring element 36 to bend to the right (as also shown in phantom lines in Fig. 1A). In this way, the physician steers the ablation electrode 16 into contact with the tissue to be ablated.

Further details of this and other types of steering mechanisms for the ablating element 10 are shown in Lunquist and Thompson U.S. Patent 5,254,088, which is incorporated into this Specification by reference.

A. <u>Actively Cooled Electrodes</u>

In the illustrated and preferred embodiment, the system 10 includes an assembly 40 for actively

clustered at the distal tip of the electrode 16. Alternatively, a single centrally located outlet aperture, or other arrangements of one or more apertures, could be provided in the distal tip of the electrode 16.

In this arrangement, the cooling assembly 40 includes a source 50 (see Fig. 1A also) of a biocompatible medium, such as saline, with or without heparin. A mechanism 52 cools the medium source 50 to a desired temperature. A supply line 54 with an in-line pump 56 supplies the cooled medium to the connection port 44 on the handle 20. The cooled medium flows through the lumen 42 and into the electrode cavity 46. The outlet apertures 48 discharge the cooled medium into the region surrounding the electrode, as Fig. 2A shows. Because the cooling medium is discharged directly into the space surrounding the electrode 16, this arrangement will be called "open" loop cooling.

The flow of cooling liquid through the electrode cavity 46 conveys heat away from the thermal mass of the electrode 16 by conductive and convective cooling. The system further includes a controller 58 (see Fig. 1A) for controlling the rate of cooling, as will be described in greater detail later.

Preferably, the flow of media through the outlet apertures 48 is sufficient to sustain a positive fluid pressure throughout use, thereby preventing clotting about the electrode 16. The size and number of outlet apertures 48 determine the magnitude of the flow resistance through the electrode 16..

The orientation of the outlet apertures 48 also affects the efficiency of the cooling effect. Preferably, the outlet apertures 48 are clustered at

Fig. 4 shows three lumens, designated 64A, 64B, and 64C. The lumen 64A adjacent the region of the electrode 16 in most intimate contact with tissue conducts a hypertonic liquid A having a relatively low resistivity at, for example, about 15 ohm·cm, compared to resistivity of blood, which is about 150 ohm·cm. The hypertonic liquid A discharged in this region therefore improves the transmission of RF energy from the electrode 16 into the tissue, regardless of whether or not the electrode 16 is also actually cooled by the liquid in the process. The other lumens 64B and 64C adjacent the region of the electrode 16 exposed to the blood pool can conduct another liquid B having a relatively high resistivity, compared to blood, of, for example, about 1500 ohm·cm. The liquid B could comprise, for example, a 5% dextrose solution. The liquid B therefore reduces the transmission of RF energy from the electrode 16 into the blood pool, again regardless of whether liquid B also cools the electrode 16 in the process. Furthermore, heparin could be supplied with liquid A through the lumen 64A adjacent the tissue-contacting region of the electrode 16 to locally reduce the incidence of clotting, while no heparin is supplied through the lumens 64B and 64C adjacent the blood-pool exposed region of the electrode 16. In this way, the volume of anticoagulant introduced into the blood pool can be more locally directed and controlled.

Fig. 5 shows another alternative embodiment of an actively cooled electrode of the "open" loop type. In this embodiment, the electrode 16 comprises a foam body 66 of an open cell porous material coated with an electrically conductive substance. The electrically conductive substance can be coated on

connection port 44 on the handle 20, with the supply lumen 74 in communication with the supply line 54 and the discharge lumen 76 in communication with the return line 72.

The distal ends of the lumens 74 and 76 communicate with a hollow cavity 78 formed in the electrode 16. The supply line 54 supplies the cooled medium through the supply lumen 74 into the cavity 78, while the return line 72 returns the medium through the discharge lumen 76 to the medium source 50 or to waste 70. As before, the flow of cooling liquid through the electrode cavity 78 conveys heat away from the thermal mass of the electrode by conductive and convective cooling.

In a "closed" loop arrangement, a pressurized gas could be used as the cooling medium. The pressurized gas would be allowed to expand within the electrode chamber, cooling the electrode by the Joule-Thompson effect. The use of a pressurized gas and the Joule-Thompson effect to cool an electrode is disclosed in Jackson et al. U.S. Patent No. 5,281,217, which is incorporated herein by reference.

3. Diode Cooling

In the alternative embodiment shown in Fig. 7, the cooling assembly 40 includes a conventional Peltier cooling diode 80 associated with the electrode 16, which is also electrically coupled by wire 32 to the generator 12. The materials of the diode 80 are complex alloys, one doped "p" and the other doped "n", like semiconductors, creating a thermocouple at the junction. An applied voltage potential passes current from a source 88 through the junction. The polarity of the voltage creates a "cold" side 82 of the diode 80, which is coupled in

to the ablation electrode 16, which is deployed within the body in contact with heart tissue. In the illustrated embodiment, when used for cardiac ablation, the generator 12 is typically conditioned to deliver up to 150 watts of power at a radio frequency of 500 kHz.

The system 90 shown in Fig. 8 also includes the source 50 of medium for cooling the electrode, as well as the mechanism 52 for cooling the medium. The mechanism 52 includes a controller 92 for establishing and maintaining a desired temperature for the cooling medium in the source.

The supply line 54 and in-line pump 56 provide communication between the source 50 and the connection port 44 on the catheter handle 20. Operation of the pump 56 conveys the cooled medium to the electrode 16, as already described. Fig. 8 shows an open loop arrangement of the type shown in Figs. 3A/B. A controller 94 coupled to the pump 56 establishes and maintains a commanded flow rate. In a closed loop system, a return line 72 conveys the medium from the electrode for return to the source 50 or to waste 70, in the manner shown in Fig. 6.

As shown in Fig. 8, the electrode 16 carries a temperature sensor 96. The sensor 96 senses instantaneous temperatures (T1) of the thermal mass of the electrode 16. The temperature T1 at any given time is a function of the power supplied to the electrode 16 by the generator 12 and the rate at which the electrode 16 is cooled by the medium.

The characteristic of a lesion can be expressed in terms of the depth below the tissue surface of the 50° C isothermal region T_{50C}, which marks the boundary of tissue rendered nonviable. Fig. 8 designates this depth as D_{50C}. The depth D_{50C} is a

about 1.3 mm into the tissue. The overall volume is a parallelpiped 8 cm long, 4 cm wide, and 4 cm thick. The model has 8144 nodes, using hexahedral elements and a nonuniform mesh.

The current density boundary conditions are set at the electrode, so that after 120 seconds (t) the maximum tissue temperature (T_{MAX}) reaches about 95° C. On the outer surface of the overall volume the potential is set to zero, and the temperature is fixed at 37° C to account for the average body temperature. At the nodes on the electrode surface the temperature is set to a value that modeled the effects of actively cooling the electrode tip. This value (T1) is varied between 4° C and 50° C. The finite element convective boundary condition at the electrode-blood interface is set to 1.8×10^{-5} Joule (J) per cubic millimeter (mm^3) second (s) Kelvin K ($J/mm^3 \cdot s \cdot K$).

COSMOS is used on a Hewlett Packard workstation to solve the electrical-thermal equations. The analysis looks at the effects of electrode cooling on lesion volume, on radio frequency power (P) required to keep T_{MAX} at about 95° C, and on the distance of the hottest tissue region beneath the tissue-electrode interface. The lesion dimensions are estimated from the volume enclosed by the 50° C isothermal surface.

The model results are corroborated with experimental data acquired using the apparatus shown in Fig. 21. A 4 cm thick slice of bovine heart H is fixed in good contact with a 144 cm^2 patch electrode EP inside a tank T filled with saline at 37° C. An ablation catheter C carrying a cooled 8F diameter/5 mm long electrode E is placed in contact with the tissue surface H at an angle of 90°. Water at about

T1 (° C)	D_{50C} (mm)	Lesion Volume (mm^3)	Distance to T_{MAX} (mm)	P (W)
4	10.2	1.25	1.51	37
10	10.1	1.19	1.4	35.4
20	9.8	1.13	1.24	33
25	9.7	1.04	1.18	32
30	9.2	0.99	1.08	31
37	9	0.89	0.97	29.5
50	8.8	0.9	0.78	26.5

Other matrices can be developed using the above-described methodology for an array of values for t and T_{MAX} to further define the D_{50C} function.

The function in Table 1 can be further supplemented by other empirically derived information showing the cooling media flow rate needed to obtain different electrode temperatures for the particular electrode, as the following Table 2 exemplifies:

TABLE 2

Average Flow Rate of Cooling Media (Cooled Water) vs. Electrode Temperature T1 at Constant Power Conditions (For 8F 5 mm ablation electrode)

T1 (° C)	30	35	40
Average Flow	9.3 ml/min	5.3 ml/min	4 ml/min

The system 90 includes a master controller 98.

the generator 12 to maintain a fixed power level P of 31 W (which does not exceed P_{MAX}) for the prescribed time t = 120 seconds. The controller 98 simultaneously controls the rate at which the electrode 16 is cooled (based upon Table 2) to establish and maintain T1 at the level called for by the function for the D_{50C} = 9.2 mm boundary selected, which in this example is T1 = 30° C (flow rate = 9.3 ml/min).

The maximum tissue temperature will continuously increase toward T_{MAX} during the targeted ablation period t, with the rate of increase depending principally upon the magnitude of P and T1. That is, the rate of tissue temperature increase with be greater at higher values of P and lower values of T1, and vice versa.

The master controller 98 can control the cooling rate in various ways. For example, the master controller 98 can control the rate of cooling by commanding the temperature controller 92 to adjust the temperature of the cooling medium over time in response to variations in T1 to establish and maintain the set T1. Alternatively, the master controller 98 can control the rate of cooling by commanding the pump controller 94 to adjust the flow rate of the cooling medium over time in response to variations of T1 to establish and maintain the set T1. The master controller 98 can also command the controllers 92 and 94 in tandem to reach the same result.

The manner in which the master controller 98 processes information pertaining to T1 to derive control signals to vary medium temperature and medium flow rate can vary. For example, the master controller 98 can employ proportional control

controller 98 achieves the desired D_{50C} without the need to sense actual tissue temperature conditions.

3. Predicting Maximum Tissue Temperature/Depth During Cooling

Fig. 9A shows a system 102 that adjusts the level of RF power delivered to a cooled electrode 16 and/or the cooling rate based upon a prediction of instantaneous maximum tissue temperature, which is designated T_{MAX} (t).

In a preferred implementation, the prediction of T_{MAX} is derived by a neural network, which samples at the current time (t) a prescribed number (k_n) of previous power levels P, previous rates at which heat has been removed to cool the electrode, and previous electrode temperature.

The heat removal rate is identified by the expression Å, where

$$Å = c \times \Delta T \times RATE$$

where:

c is the heat capacity of the cooling medium used (in Joules (J) per kilogram (kg) Kelvin (K), or J/kg K)

ΔT is the temperature drop in the cooling medium during passing through the electrode 16 (K), and

RATE is the mass flow rate of the cooling medium through the electrode (kg/sec).

The heat transmitted by the ablation electrode to the tissue is the difference between the heat generated by Joule effect and the heat removed by active cooling. At a given temperature T1 and flow rate of cooling medium, the magnitude of Å increases as RF power delivered to the electrode 16 increases.

contact with the electrode 16, there is no third temperature sensing element 108. In this case, ΔT is computed as follows:

$$\Delta T = T1 - T_{IN} \qquad \text{Open System}$$

In systems where environmental variables are closely controlled, the prediction of T_{MAX} may be derived from sampling at the current time (t) a prescribed number (k_n) of previous power levels P and previous electrode temperatures, without sampling Å.

In Fig. 9A, the master controller 98 is coupled to the RF generator, the temperature sensing elements 104, 106, and 108 (or 104 and 106 in an open system), the cooling controller 92, and the pump controller 94.

The controller 98 includes a neural network predictor 144 (see Fig. 9B). The predictor 144 can comprise a two-layer neural network, although more hidden layers could be used. The predictor 144 receives as inputs a first set of k_1 of weighted past samples of Å, {Å (t-1) to (t-k_1)}; a second set of k_2 of weighted past samples of P, {P (t-1) to (t-k_2)}; and a third set of k_3 samples of T1, {T1 (t-1) to (t-k_3)}. The number of samples in the sets $k_{1,2,3}$ can be varied, according to the degree of accuracy required. As an example, k_1 and k_2 are preferably in the range of 5 to 20. k_3 can be selected equal to 1.

The predictor 144 can be variously configured. In the illustrated embodiment, the predictor 144 comprises a two layer neural network, although more hidden layers could be used.

In this implementation, the predictor 144 includes first and second hidden layers and four neurons, designated $N_{(L,X)}$, where L identifies the

targeted magnitude, or the value of TT_{SET} can vary over time to define a set temperature curve, which can be either linear or nonlinear. Further details of using set temperature curves are disclosed in U.S. Patent Application Serial No. 08/266,023, filed June 27, 1994, and entitled "Tissue Heating and Ablation Systems and Methods Using Time-Variable Set Point Temperature Curves for Monitoring and Control."

For $T1_{SET}$, the preferred embodiment takes into account the relationship between electrode temperature T1 and increases in lesion volume shown in Fig. 1D, selecting as the desired $T1_{SET}$ a temperature below about 25° C and, most preferable, between about 10° C and about 25 C.

The value P_{MAX} is the highest allowed power level, based upon considerations already stated.

The master controller 98 periodically derives T_{MAX} (t) and compares T_{Max} (t) to TT_{SET} (t). Based upon this comparison, the master controller 98 derives a demand power output, taking into account P_{MAX}, while cooling to maintain $T1_{SET}$. The demand power output represents the magnitude of the radio frequency power that should be supplied to the electrode 16 to establish and contain the desired maximum tissue temperature TT_{SET} at a fixed value or along a set linear or nonlinear curve.

Alternatively, the master controller 98 could maintain a fixed power level below P_{MAX} and adjust the cooling rate Å based upon T_{MAX} (t) to contain TT_{SET} at a fixed value or along a set curve. As before described, the master controller 98 can control the cooling rate by commanding the temperature controller 92 to adjust the temperature of the cooling medium over time, or by commanding the pump controller 94 to adjust the flow rate of the cooling

ml/min, a sensed power P of 31 W, and a sensed electrode temperature T1 of 30° C, Tables 1 and 2 would infer that T_{MAX} would be 95° C at an ablation time (t) of 120 seconds. In this implementation the inferred maximum tissue temperature becomes T_{MAX}. Power and/or cooling rate are then controlled to contain T_{MAX} at a fixed value or along a set curve.

3. Sensing Actual Maximum Tissue Temperature/Depth During Cooling

In the embodiments shown in Figs. 10 to 12, the cooled ablation electrode 16 carries at least one temperature sensing element 110 for sensing actual tissue temperature. In these embodiments, the power that the RF generator 12 applies to the electrode 16 is set, at least in part, by the actual tissue temperature conditions sensed by the element 110.

In the illustrated embodiment, the temperature sensing element 110 comprises a conventional small bead thermistor 112 with associated lead wires 114. In a preferred implementation, the thermistor 42 comprises a 0.55 mm bead thermistor commercially available from Thermometrics (Edison, New Jersey), Part Number AB6B2-GC16KA143E/37° C-A.

It should be appreciated that other types of temperature sensing elements can also be used. For example, a thermocouple could be used as the temperature sensing element. In a preferred implementation, the thermocouples are constructed by either spot welding or by laser stripping and welding the different metals together to form the thermocouple junction. When a thermocouple serves as the temperature sensing element, a reference thermocouple must be used. The reference thermocouple may be placed in the handle 20 or exposed to the blood pool in the manner disclosed in

handle 20 (see Fig. 15A). There, the lead wires 114 electrically couple to the cable 28 extending from the handle 20. The cable 28 connects to the generator 12 and transmits the temperature signals from the thermistor 112 to the generator 12.

In the embodiment illustrated in Figs. 10 to 12, the ablation electrode 16 includes an interior well 118 at its tip end. The temperature sensing element 110 occupies this well 118. The sensing element 110 shown in Figs. 10 to 12 extends beyond the tip of the electrode 16 to project beneath the surface of the endocardium. The sensing element 110 is thereby positioned to sense actual sub-surface tissue temperature conditions.

In the illustrated and preferred embodiment, the sub-surface temperature sensing element 110 is enclosed within a thermally conducting cap 120 (see Figs. 10 and 11). The cap 120 comprises a material having a high thermal conductivity that is at least 1.0 watt (W) per meter (m) Kelvin (K), or 1.0 W/m K. Metallic materials like stainless steel, gold, silver alloy, platinum, copper, nickel, titanium, aluminum, and compositions containing stainless steel, gold, silver, platinum, copper, nickel, titanium, and aluminum possess this degree of thermal conductivity. For example, stainless steel has a thermal conductivity of about 15 W/m K, and platinum has a thermal conductivity of about 71 W/m K. This thermal conductivity is significantly higher than the thermal conductivity of conventional polymer potting material surrounding the temperature sensor 110. For example, silicon rubber has a thermal conductivity of only about 0.13 W/m K, and polyurethane has a thermal conductivity of only about 0.026 W/m K.

characteristics, creating an isothermal surface around the sub-surface sensing element 110 in thermal equilibrium with the surrounding tissue temperature conditions. The cap 120 also provides added strength to resist bending or fracture during manufacturing and handling.

In the illustrated and preferred embodiment, a thermal and electrically insulating barrier 142 forms an interface between the interior wall of the well 118 and the side of the cap 120 that occupies it. In a preferred embodiment, the barrier 142 comprises polyamide adhered about the sidewall of the cap 120 using FMD-14 to serve as an electrical insulator. The barrier 142 also comprises polyester shrink tubing secured by heat shrinking about the polyamide to serve as a thermal insulator.

In the illustrated and preferred embodiment, a thermal insulating tube 144 also lines the interior of the well 118 . The tube 144 further thermally insulates the temperature sensing element 40 from the thermal mass of the electrode 16. In the illustrated and preferred embodiment, the thermistor-containing cap 120 and associated barrier 142 are affixed by potting within the electrode well using cyanoacrylate FMD-13 (Loctite Corporation, Newington, Connecticut).

Therefore, the temperature condition sensed by the sensing element 40 within the cap 120 closely represents the actual tissue temperature condition that the cap 120 contacts.

EXAMPLE

The thermal sensitivity of a temperature sensing element enclosed in a thermally conductive carrier according to the invention (Sensor 1) was compared to the thermal sensitivity of a temperature sensing

TABLE 3

Comparison of the Thermal Sensitivity of a Temperature Sensor Carried Within a Thermal Conductive Surface to the Thermal Sensitivity of a Temperature Sensor Without a Thermal Conductive Surface

	VERTICAL POSITION	HORIZONTAL POSITION
SENSOR 1 (With Thermal Conductive Surface)	59° C	40°C
SENSOR 2 (Without Thermal Conductive Surface)	40°C	39°C

The above Table shows that Sensor 2 is not sensitive to the actual temperature of the 60° C heat source. Regardless of its orientation, Sensor 2 continues to sense the 40° C temperature of the thermal mass of the electrode itself (the remainder of the heat energy of the source being dissipated by the surrounding water bath).

In contrast, Sensor 1 shows significant sensitivity with respect to its contact orientation with the 60° C heat source. When held horizontally, out of direct contact with the heat source, Sensor 2, like Sensor 1, senses the 40° C temperature of the thermal mass of the electrode itself. However, when held vertically, in direct contact with the heat source, Sensor 1 essentially senses the actual temperature of the heat source, and not the temperature of the electrode. The cap encapsulating

the cap 120 presents a sharpened distal end 124 that actually penetrates the endocardium. By causing the cap 120 to actual penetrate the endocardium, better uniform tissue contact is achieved, both beneath the surface about the temperature sensing element 110 and at the surface along the electrode.

The temperature sensing element 110 can project into the tissue at any depth desired, depending upon the tissue morphology of the individual patient and the experience and judgment of the attending physician, provided, of course, that transmural penetration of the heart wall does not occur.

In the preferred embodiment (see Figs. 13 and 14), the temperature sensing element 110 is movable by the physician between a retracted position within the electrode well 118 (shown in Fig. 13) and an extended position outside the electrode well 118 (shown in Fig. 14) projecting into tissue. In Figs. 13 and 14, the temperature sensing element 110 is shown to have a blunt distal end 124, although a sensing element 110 having a sharpened distal end could also be used.

The movable nature of the temperature sensing element 110 shown in Figs. 13 and 14 provides added protection against bending or fracture of the element until the moment of use. The element 110 can be retained in a retracted, not exposed position during handling outside the body and while being deployed to the desired site within the body.

The movement of the temperature sensing element can be accomplished in various ways. In the embodiment shown in Figs. 13 and 14, a stylet 126 extends through the catheter body 22 within a braided protective sleeve 128 made of, for example, polyimide or stainless steel. The proximal end of

the retracted and extended positions.

In this arrangement (see Fig. 15B), the distal cap end 124 can itself be threaded with helical lands 146. Upon rotational advancement of the sensing element 110 by the stylet 126, the helical lands 146 engage tissue to better anchor the element 110 for temperature sensing. Alternatively (see Fig. 15C), the stylet 126 can be attached to a carrier 150 configured as a cork-screw. Like the helical lands 146, the cork-screw carrier 150 engages tissue during rotation as the stylet 126 is advanced forward by rotation. As Fig. 15C shows, the temperature sensing element 110 is secured in thermal conductive contact with the cork-screw carrier 150 near its distal tip.

In the illustrated and preferred embodiment, the distal cap end 124 and the distal tip of the electrode 16 are marked with a fluoroscopically dense material. In this way, the travel of the temperature sensing element 110 into the tissue can be monitored by fluoroscopy as the physician incrementally advances the element 110.

Alternatively, the stylet 126 can be advanced without rotation. In this arrangement (see Fig. 16), the proximal end of the stylet 126 includes a series of ribs 152, which successively make releasable, snap-fit engagement with detent 154 in the handle 20. As the physician moves the stylet 126 in a linear (push-pull) direction, the detent 154 captures the ribs 152 one at a time, releasing the captured rib 152 in response to further linear force. Like the rotating stylet 126 shown in Fig. 8, the linear (push-pull) stylet 126 shown in Fig. 16 permits controlled, incremental movement of the sensing element 110 into and out of tissue contact.

the length of the housing 156. The sensing of the relative temperature gradient permits the identification along the gradient of the maximum tissue temperature region for control purposes, although the temperatures sensed by the elements 112(1)/112(2)/112(3) will not directly represent actual tissue temperatures.

If a more direct correspondence between sensed and actual tissue temperatures is required, the housing 156 (see Fig. 17B) can include spaced bands 158(1), 158(2), and 158(3) of thermal conductive material having thermal conductivity well above the contacted tissue, of at least 1.0 W/m K, as already described. The spaced bands 158(1), 158(2), 158(3) establish localized regions of thermal conductive contact between individual sensing element 112(1), 112(2), and 112(3) and tissue immediately adjacent to the respective band. Thermal insulating material 160 substantially isolates the spaced bands 112(1), 112(2), and 112(3) from thermal conductive contact with each another. The thermally isolated bands 112(1), 112(2), and 112(3), each with a relatively high thermal conductivity, more accurately obtain the actual tissue temperature gradient along the length of the housing 156, than when materials with lower thermal conductivities are used.

In either embodiment, the multiple, axially stacked thermocouples 112(1), 112(2), and 112(3) allow the physician to obtain and monitor a profile of temperate conditions at different depths beneath the tissue surface. The physician can manually select for ablation control purposes the one thermocouple located in the hottest sub-surface temperature region. Alternatively, an automated control mechanism can automatically compare

controller 164 incrementally moves the stylet 126, while taking instantaneous measurements of temperature condition at each increment, to seek the sub-surface tissue region where the highest temperature conditions exist. The controller 164 outputs the sensed highest temperature while incrementally adjusting the position of the element 110, as necessary, to maintain it in the highest sub-surface temperature region.

Various control processes can be used to command movement of the stylet 126 to position the temperature sensing element 110 in the region of highest sub-surface tissue temperature. For example, proportional control principles, proportional integral derivative (PID) control principles, adaptive control, neural network, and fuzzy logic control principles can be used. Fig. 22 shows a representative control process 166 that the feedback controller 164 can use.

While incrementally moving the stylet 126, the process 166 inputs instantaneous tissue temperatures TT(t) sampled by the element 110 at a prescribed time interval Δt. Δt can vary according to the degree of accuracy and sensitivity required. For example, Δt can be 5 seconds.

The process 166 derives a temperature difference ΔTT between successive samples ($\Delta TT = TT(t) - TT(t-1)$). The process 166 employs prescribed course and fine differential temperature threshold values, respectively E_1 and E_2, to home in on the maximum tissue temperature. The differential threshold values can vary, again according to the accuracy and sensitivity required. For example, the course differential threshold value E_1 can be set to 5° C, and the fine differential threshold value E_2 can be

receives from the physician, via the input device 100, a desired tissue temperature value TT_{SET}, a desired electrode temperature $T1_{SET}$, and a P_{MAX}. As earlier disclosed, the set temperature value TT_{SET} represents the desired hottest sub-surface tissue temperature that the physician wants to maintain at the ablation site, to thereby control the incidence of micro-explosions. TT_{SET} can comprise a fixed value or a set linear or nonlinear curve varying tissue temperature over time.

Likewise, the value $T1_{SET}$ represents a hottest temperature for the thermal mass of the cooled ablation electrode 16, which, as earlier stated, is believed to be between about 10° C and about 25° C.

The value P_{MAX} is the highest allowed power level, also based upon considerations already stated.

The master controller 98 periodically compares the sensed maximum tissue temperature T_{MAX} to TT_{SET}. Based upon this comparison, the master controller 98 derives a demand power output, taking into account P_{MAX}, while cooling to maintain $T1_{SET}$. The demand power output represents the magnitude of the radio frequency power that should be supplied to the electrode 16 to establish and maintain the desired maximum tissue temperature TT_{SET}.

Alternatively, the master controller 98 could maintain a fixed power level below P_{MAX} and adjust the cooling rate based upon sensed T_{MAX} to achieve TT_{SET}. As before described, the master controller 98 can control the cooling rate by commanding the temperature controller 92 to adjust the temperature of the cooling medium over time, or by commanding the pump controller 94 to adjust the flow rate of the cooling medium over time, or by commanding the

WE CLAIM:

1. An apparatus for ablating body tissue comprising

an electrode for contacting tissue at a tissue-electrode interface to transmit ablation energy at a determinable power level,

an element to remove heat from the electrode at a determinable rate,

a processing element to sample the power level at which the electrode transmits ablation energy and the temperature of the electrode, and to derive therefrom a prediction of the maximum tissue temperature condition occurring beneath the tissue-electrode interface.

2. An apparatus for ablating body tissue comprising

an electrode for contacting tissue at a tissue-electrode interface to transmit ablation energy at a determinable power level,

an element to remove heat from the electrode at a determinable rate,

a processing element to sample the power level at which the electrode transmits ablation energy , the temperature of the electrode, and the rate at which heat is removed from the electrode, and to derive therefrom a prediction of the maximum tissue temperature condition occurring beneath the tissue-electrode interface.

3. An apparatus for ablating body tissue comprising

an electrode for contacting tissue at a tissue-electrode interface to transmit ablation energy at a determinable power level,

an element to remove heat from the electrode at a determinable rate, and

as a result of thermal conductive contact with the electrode.

9. An apparatus according to claim 8 wherein the processing element controls the rate at which heat is removed from the electrode based, at least in part, upon the maximum tissue temperature prediction.

10. An apparatus according to claim 8 wherein the heat removal rate is expressed as Å, where where:

$$Å = c \times \Delta T \times RATE$$

c is the heat capacity of the cooling medium (in J/kg K),

ΔT is the temperature drop in the cooling medium due to thermal conductive contact with the electrode (in K), and

RATE is the mass flow rate of the cooling medium when coming into thermal conductive contact with the electrode (in kg/sec).

11. An apparatus according to claim 10 wherein the processing element controls the rate at which heat is removed from the electrode based, at least in part, upon the maximum tissue temperature prediction.

12. An apparatus according to claim 1 or 2 or 3 wherein the processing element includes a temperature sensing element in thermal conductive contact with the electrode to sense temperature of the electrode.

13. An apparatus according to claim 1 or

ablating tissue,

a cooling element to cool the electrode by directing a cooling medium into thermal conductive contact with the electrode,

a controller coupled to the generator to supply power to the generator, the controller comprising

a first sensing element to measure temperature at the electrode,

a second sensing element to measure power supplied to the generator, and

a processing element for sampling temperature sensed by the first sensing element and for sampling power sensed by the second sampling element and to derive therefrom a prediction of the maximum tissue temperature condition occurring beneath the tissue-electrode interface and for generating a signal to control the rate that the cooling element cools the electrode based, at least in part, upon the maximum tissue temperature prediction.

17. An apparatus according to claim 16

wherein the processing element generates a signal to control power supplied to the generator based, at least in part, upon the maximum tissue temperature prediction.

18. An apparatus for supplying energy to an electrode for ablating tissue comprising

a generator adapted to be coupled to an electrode to supply energy to the electrode for ablating tissue,

a cooling element to cool the electrode by directing a cooling medium into thermal conductive contact with the electrode,

a controller coupled to the generator to

power supplied to the generator,

a third sensing element to measure temperature variations in the cooling medium as a result of thermal conductive contact with the electrode, and

a processing element for sampling temperature sensed by the first sensing element, for sampling power sensed by the second sampling element, and for sampling temperature variations in the cooling medium sensed by the second sensing element, and to derive therefrom a prediction of the maximum tissue temperature condition occurring beneath the tissue-electrode interface and for generating a signal to control the rate at which the cooling element cools the electrode based, at least in part, upon the maximum tissue temperature prediction.

20. An apparatus according to claim 19

wherein the processing element generates a signal to control power supplied to the generator based, at least in part, upon the maximum tissue temperature prediction.

21. An apparatus according to claim 18 or 19

wherein the processing element derives a heat removal rate expressed as Å, where

$$Å = c \times \Delta T \times RATE$$

where:

c is the heat capacity of the cooling medium (in J/kg K),

observed relationship among maximum tissue temperature below the tissue-electrode interface and a set of predetermined operating conditions including electrode temperature and power; and to derive from the comparison a prediction of the maximum tissue temperature condition occurring beneath the tissue-electrode interface; and for generating a signal to control power supplied to the generator based, at least in part, upon the maximum tissue temperature prediction.

25. An apparatus according to claim 24

wherein the element that removes heat cools the electrode by directing a cooling medium into thermal conductive contact with the electrode,

wherein the processing element also samples the rate at which the cooling medium is directed into thermal conductive contact with the electrode, and

wherein the predetermined operating conditions that the function correlates includes the rate at which the cooling medium is directed into thermal conductive contact with the electrode.

26. An apparatus for supplying energy to an electrode for ablating tissue comprising

a generator adapted to be coupled to an electrode to supply energy to the electrode for ablating tissue,

a cooling element to cool the electrode by directing a cooling medium into thermal conductive contact with the electrode,

a controller coupled to the generator to supply power to the generator, the controller comprising

a first sensing element to measure temperature at the electrode,

thermal conductive contact with the electrode.

29. An apparatus according to claim 27 wherein the processing element derives a heat removal rate expressed as Å, where

$$Å = c \times \Delta T \times RATE$$

where:

c is the heat capacity of the cooling medium (in J/kg K),

ΔT is the temperature drop in the cooling medium due to thermal conductive contact with the electrode (in K), and

RATE is the mass flow rate of the cooling medium when coming into thermal conductive contact with the electrode (in kg/sec).

30. A method for ablating body tissue comprising the steps of

supplying ablation energy to an electrode,

conducting heat from the electrode,

sensing temperature at the electrode,

sensing power transmitted by the electrode, and

deriving from the sensed temperature and sensed power a prediction of the maximum tissue temperature condition occurring beneath the tissue-electrode interface.

31. A method for ablating body tissue comprising the steps of

supplying ablation energy to an electrode,

34. A method according to claim 30 or 31 or 32

and further including the step of controlling the rate at which heat is conducted from the electrode based, at least in part, upon the predicted maximum tissue temperature condition.

35. A method according to claim 34

wherein the step of conducting heat removes heat by directing a cooling medium into thermal conductive contact with the electrode.

36. A method according to claim 35

wherein the rate at which heat is removed from the electrode is sensed based upon temperature variations in the cooling medium as a result of thermal conductive contact with the electrode.

37. A method according to claim 35

wherein the rate at which heat is conducted from the electrode is derived from a heat removal rate expressed as Å, where

$$Å = c \times \Delta T \times RATE$$

where:

c is the heat capacity of the cooling medium (in J/kg K),

ΔT is the temperature drop in the cooling medium due to thermal conductive contact with the electrode (in K), as sensed by the second sensing element, and

RATE is the mass flow rate of the

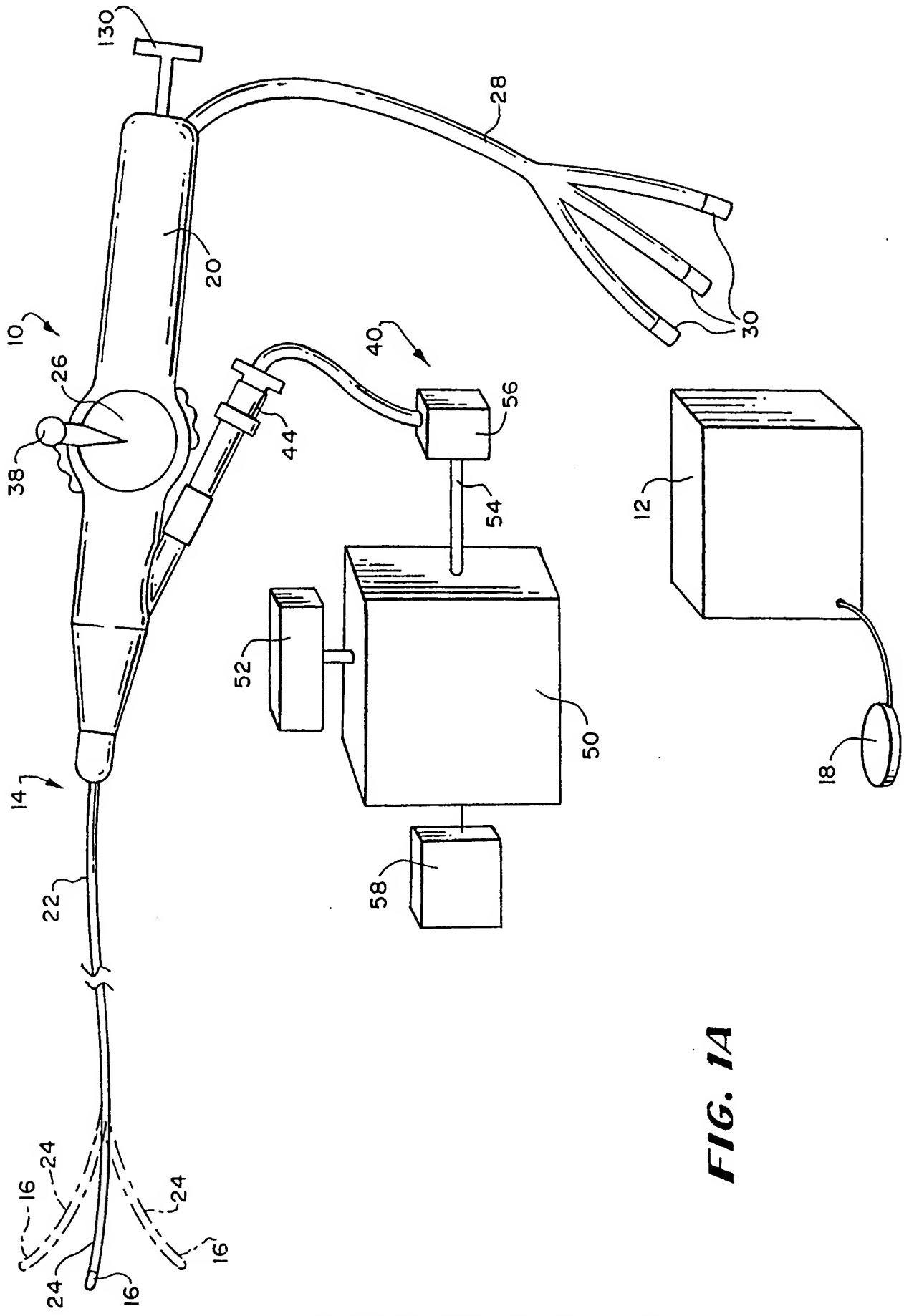
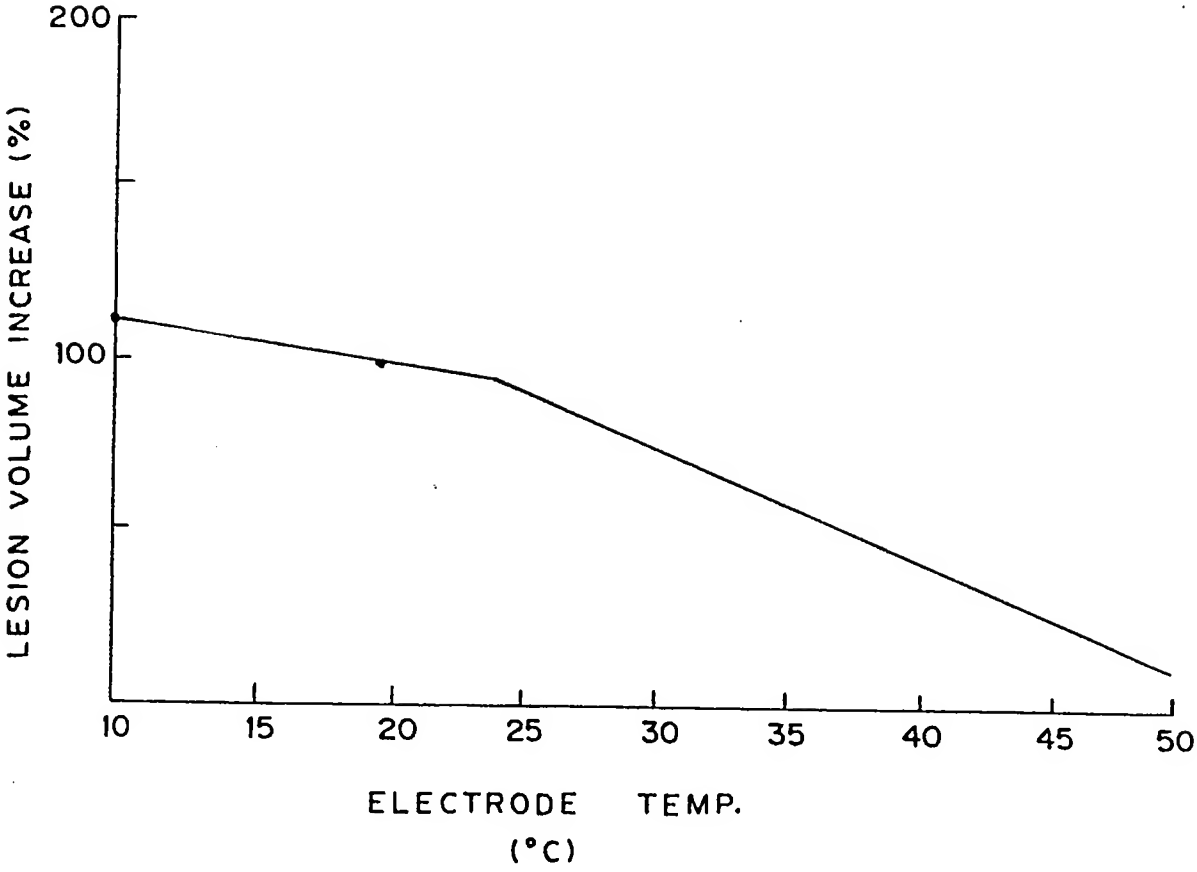


FIG. 1A

FIG. 1D



LESION VOLUME INCREASE
VS.
ELECTRODE TEMPERATURE
(MAXIMUM TISSUE TEMPERATURE
AT 94°C)

FIG. 3A

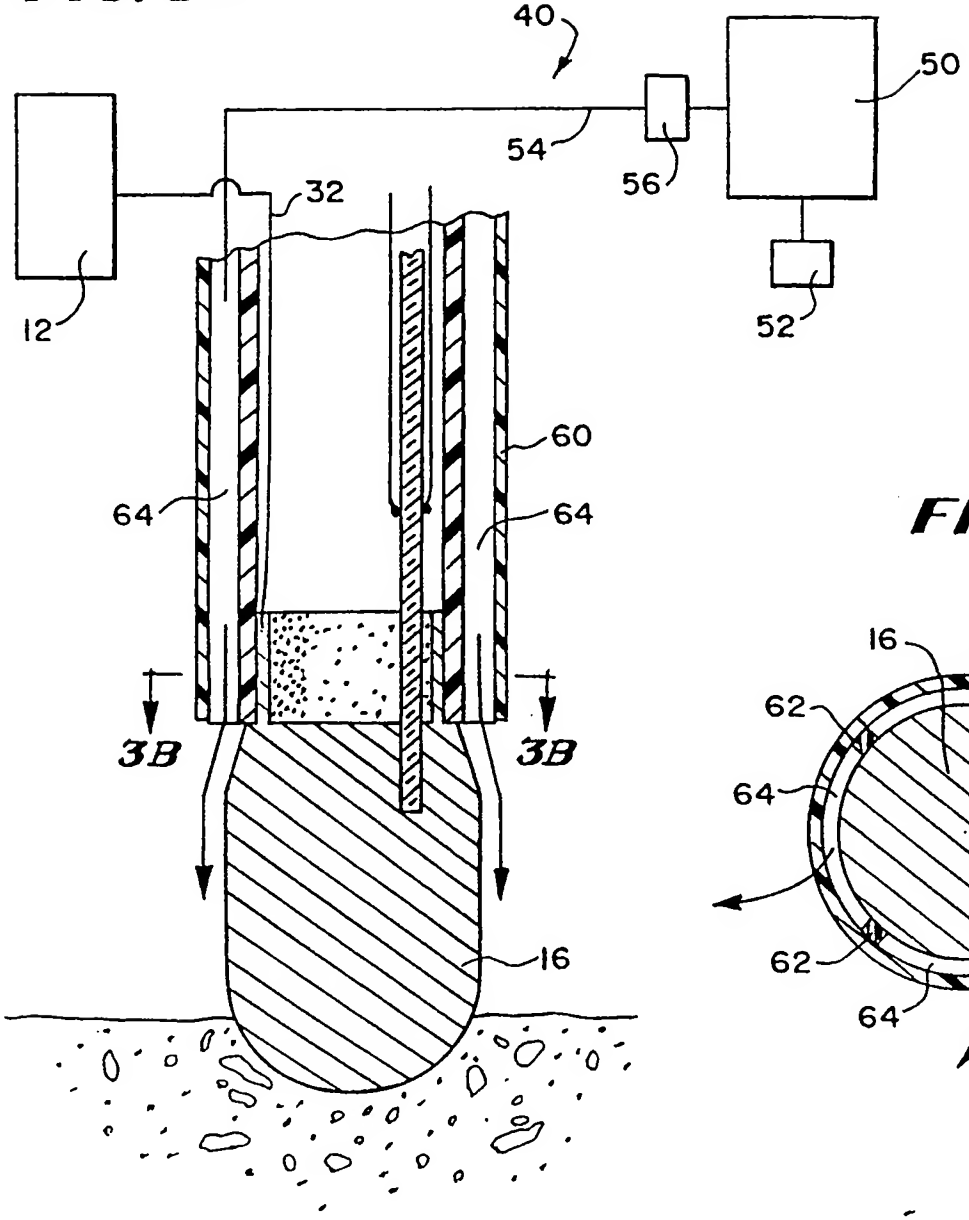
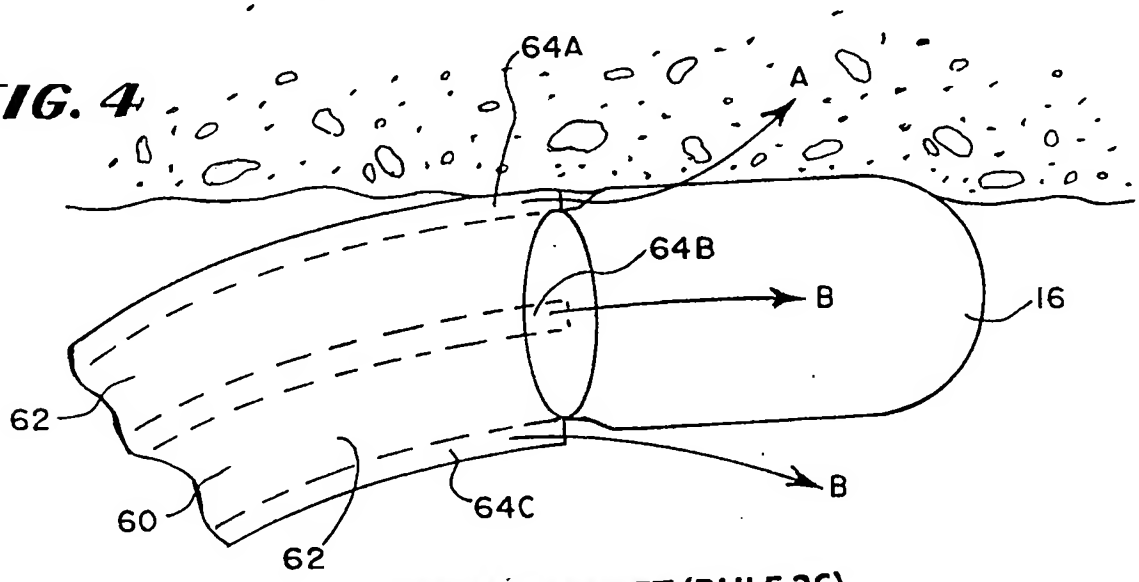


FIG. 3B

FIG. 4



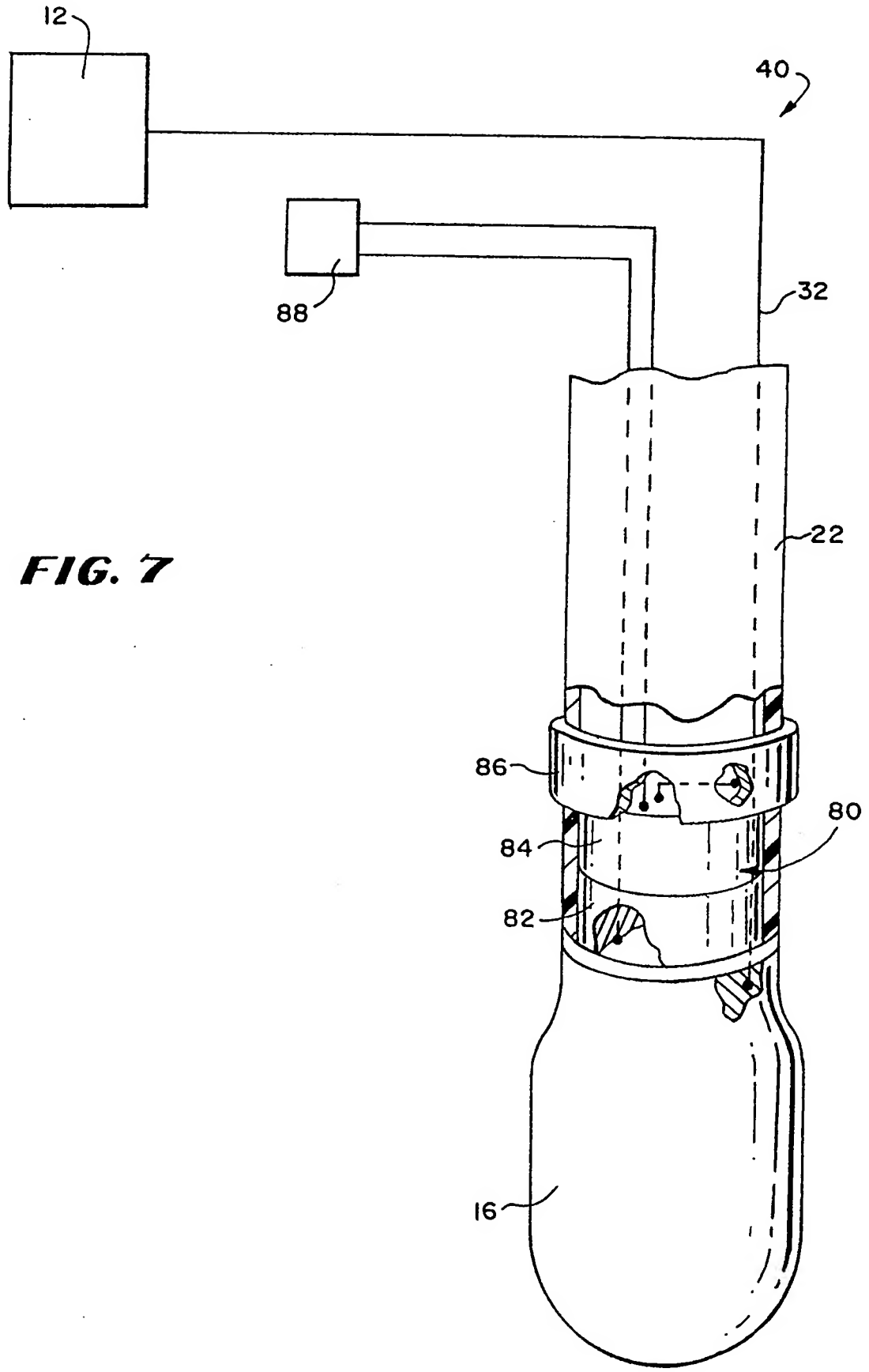


FIG. 7

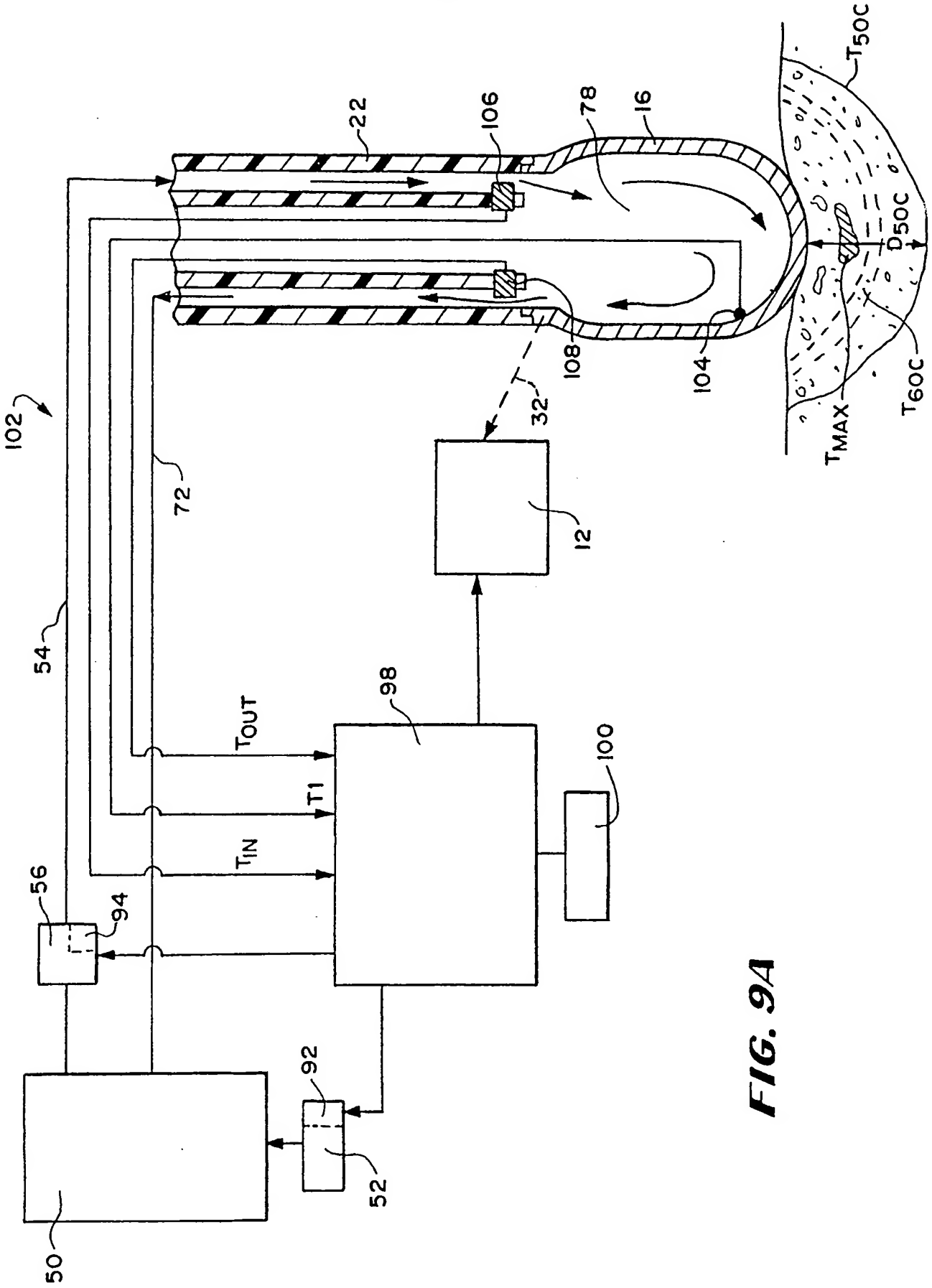

T50C
22
106
78
16
D50C
108
104
T60C
TMAX
32
102
72
12
54
98
TOUT
T1
TIN
100
56
94
92
52
50

FIG. 9A

FIG. 10

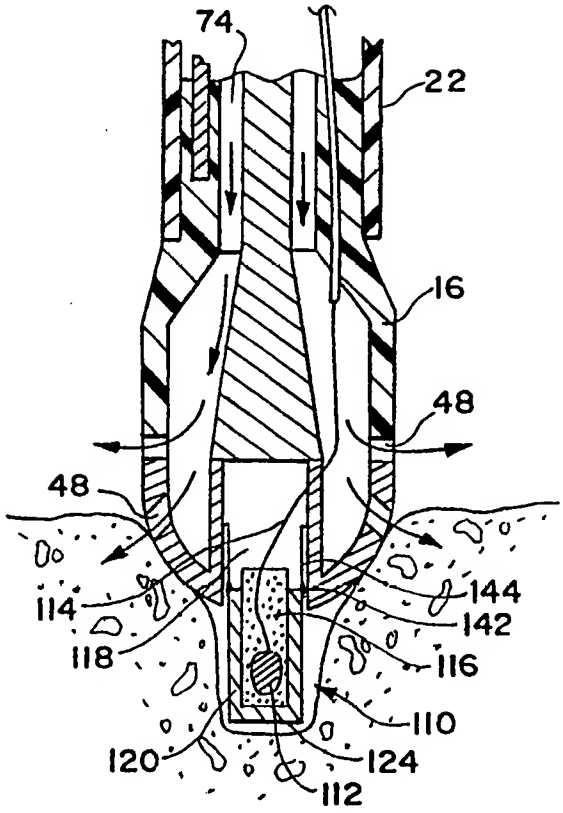


FIG. 11

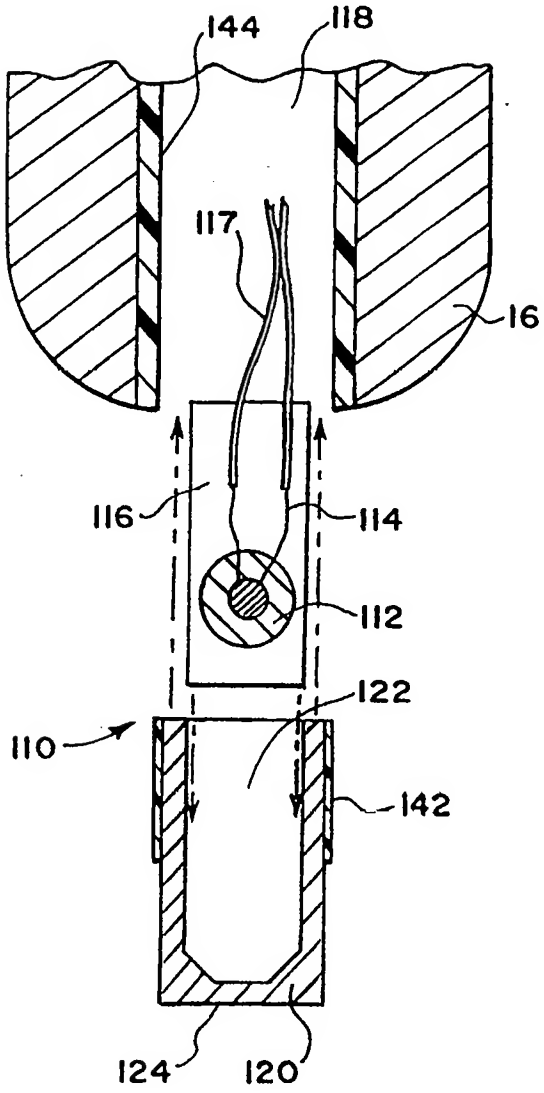


FIG. 12

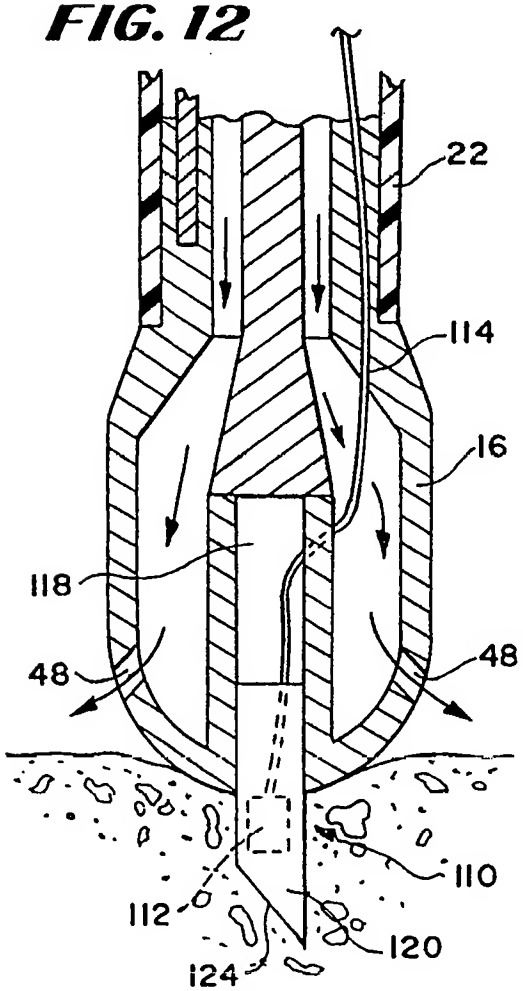


FIG. 15A

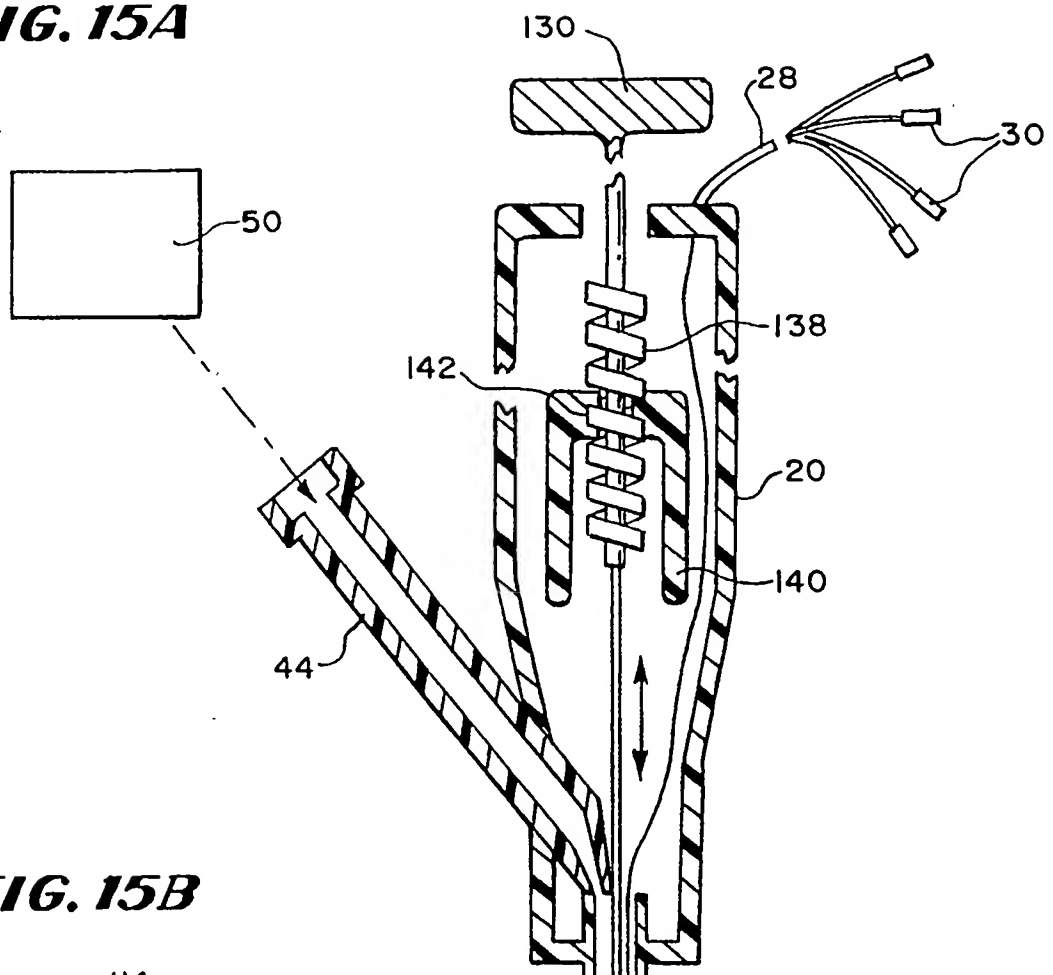
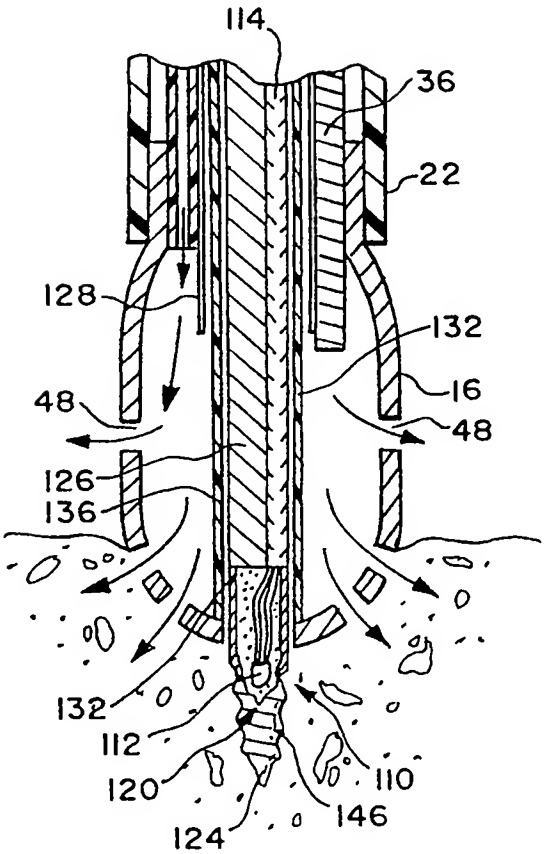


FIG. 15B



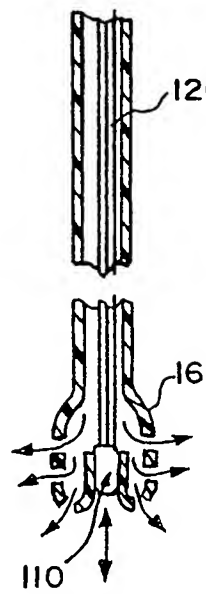


FIG. 15C

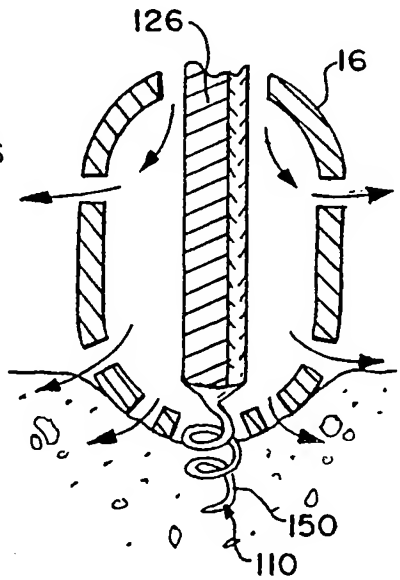
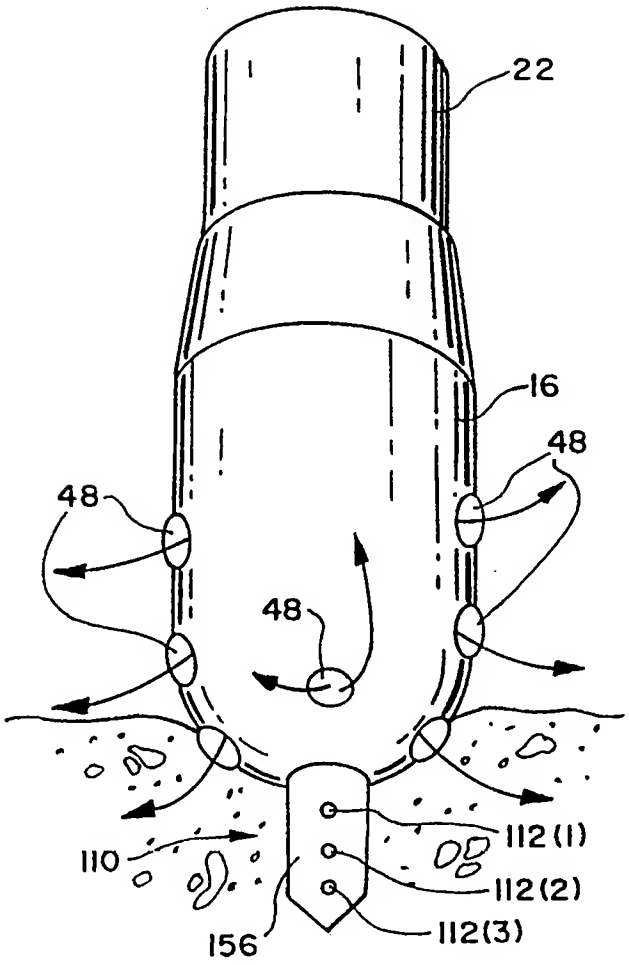


FIG. 17A



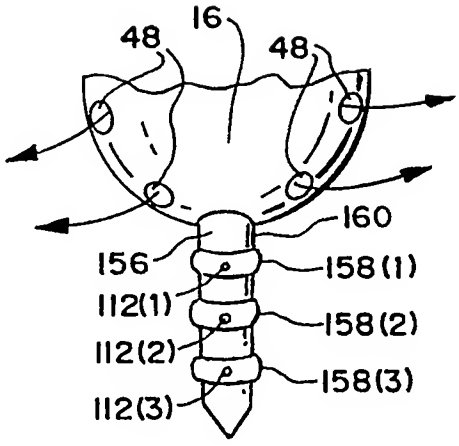


FIG. 17B

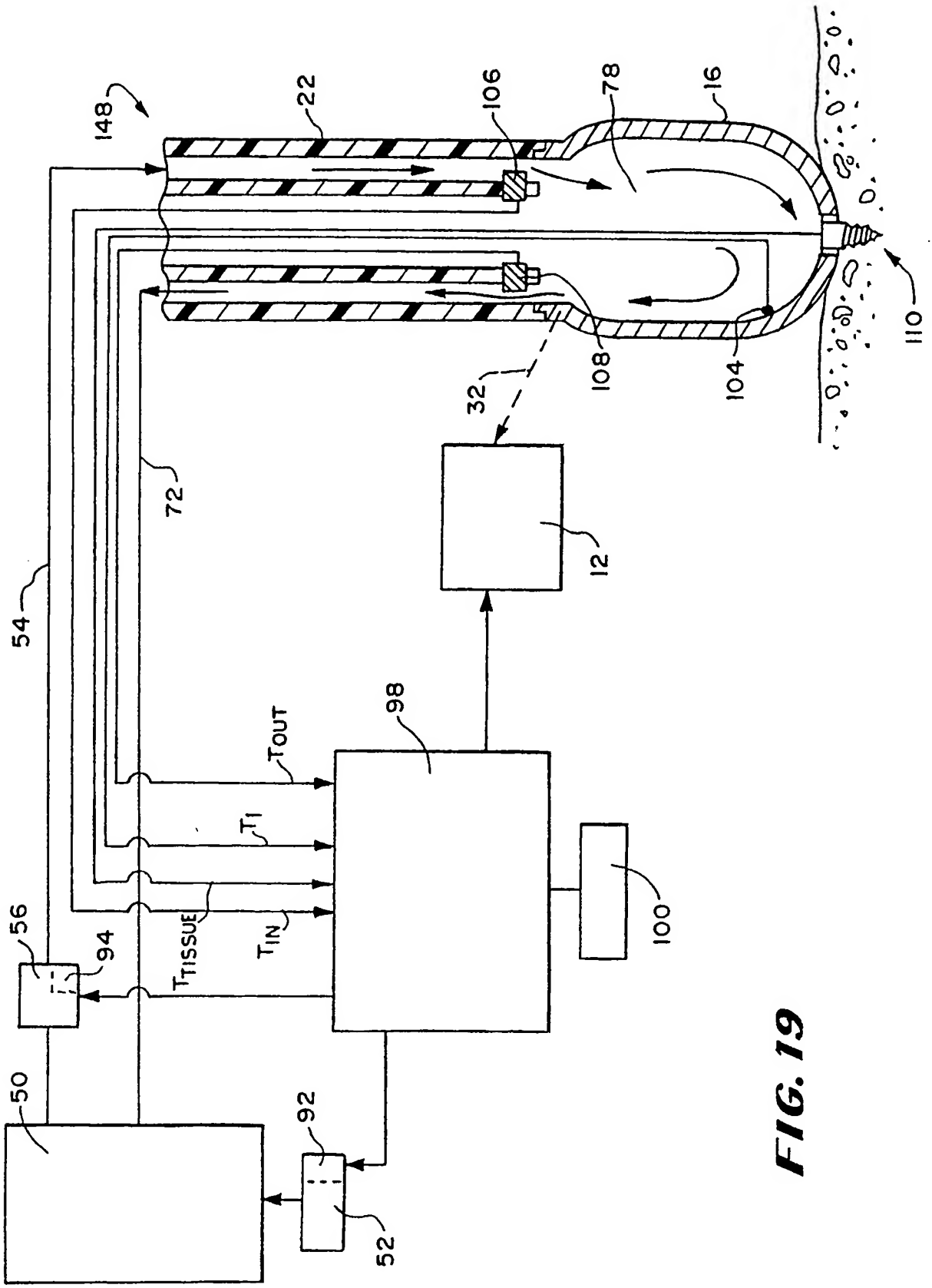
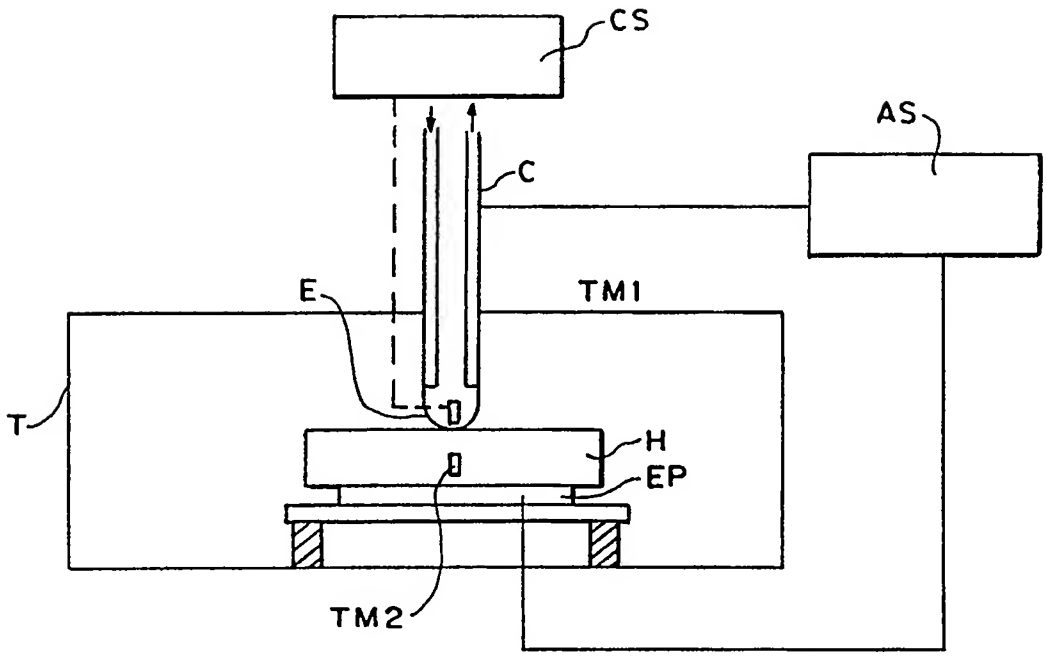

148
22
106
78
16
110
108
104
32
72
12
54
98
T_{OUT}
T_I
T_{TISSUE}
T_{IN}
56
94
100
50
92
52

FIG. 19

FIG. 21



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/05978

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/39
US CL :606/42

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/21, 22; 606/27-31, 41, 42, 45-50; 607/96, 98, 100-102, 115, 116, 122

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 5,330,518 (NEILSON ET AL.) 19 July 1994, see whole document.	1-9, 12, 13, 15-20, 22, 24-28, 30-36, 38, 39, 41 --- 10, 11, 14, 21, 23, 29, 37, 40
X	US, A. 5,334,193 (NARDELLA) 02 August 1994, see whole document.	1-7, 12, 13
A, P	US, A, 5,423,811 (IMRAN ET AL.) 13 June 1995, see whole document.	1-41

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 12 JUNE 1996	Date of mailing of the international search report 03 JUL 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MICHAEL PEFFLEY Telephone No. (703) 308-4305